

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Doc. No. 087147-0450

Reissue Application No. (not yet assigned))

Inventors:

Yoshiyuki INADA *et al.*

Patent No. 6,348,481

Examiner: Deborah C. Lambkin

Filed: Herewith

Art Unit: 1626

FOR: PHARMACEUTICAL COMPOSITION FOR ANGIOTENSIN-II MEDIATED DISEASES

BROADENING REISSUE DECLARATION UNDER 37 C.F.R. § 1.175(a)

Assistant Commissioner for Patents
P.O. Box 1450
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We, Yoshiyuki Inada and Keiji Kubo, declare that:

1. Our residence, post office address, and citizenship are stated below next to our names.
2. We believe we are the original, joint, and first inventors of the subject matter described and claimed in our U.S. Patent 6,348,481 and in the foregoing specification for which a reissue patent is sought on the invention entitled "PHARMACEUTICAL COMPOSITION FOR ANGIOTENSIN-II MEDIATED DISEASES."
3. We have reviewed and understand the contents of the above-identified specification, including the new claims added by way of a Preliminary Amendment filed herewith.
4. We acknowledge the duty to disclose information which is material to examination of the application in accordance with 37 C.F.R. §1.56(a).
5. U.S. Patent No. 6,348,481 claims priority to the following U.S. patent applications and foreign patent applications:

This Application is a Divisional of 09/563,855 filed 05/04/2000, which is a Continuation of 09/287,167, filed 04/06/1999, which is a Continuation of 08/883,040, filed 06/26/1997, which is a Divisional of 08/351,011, filed 12/07/1994, which is a Continuation-

in-part of 08/254,541, filed 06/06/1994, which claims priority to JP 133524-1993, filed 06/07/1993.

6. We believe originally issued United States Letters Patent No. 6,348,481 ("481 patent") may be partly inoperative or invalid by reason of the Petitioner claiming more or less than Petitioner had the right to claim in the patent and for the reason that Petitioner failed to provide claims directed to a subgenus of the originally disclosed invention. The error in failing to provide claims directed to a subgenus which comprises one of the three recited species in combination with a compound having diuretic activity or a compound having calcium antagonist activity was discovered as a result of discussions involving Petitioner's attorneys. During these discussions, it was discovered that claims directed to this subgeneric invention were lacking in the scope of coverage. It was error for Petitioner to omit a set of claims directed to this subgenus which comprises one of the three recited species in combination with a compound having diuretic activity or a compound having calcium antagonist activity.

Claims 4-10 are added in a concurrently filed preliminary amendment to correct this deficiency. Claim 4 is directed to a pharmaceutical composition which comprises at least one of (\pm) -1-(cyclohexyloxycarbonyloxy)ethyl 2-ethoxy-1-[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylate, 2-ethoxy-1-[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylic acid, or 2-ethoxy-1-[[2'-(2,5-dihydro-5-oxo-1,2,4-oxadiazol-3-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylic acid, or a pharmaceutically acceptable salt thereof, in combination with a compound having diuretic activity or a compound having calcium antagonistic activity.

The species, (\pm) -1-(cyclohexyloxycarbonyloxy)ethyl 2-ethoxy-1-[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylate, is recited in the specification at column 15, lines 24-26, column 17, lines 40-42 and lines 55-57, column, 19, lines 5-7 and lines 21-23, column 20, lines 54-57, column 21, lines 5-8 and lines 59-62 and column 22, lines 16-19.

The species, 2-ethoxy-1-[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylic acid, is recited in the specification at column 16, lines 57-58, column 17, lines 5-7, as the disodium salt at column 18, lines 6-8, column, 19, lines 60-62, column 20, lines 18-20 and lines 35-37 and column 21, lines 25-27 and lines 40-42.

The species, 2-ethoxy-1-[[2'-(2,5-dihydro-5-oxo-1,2,4-oxadiazol-3-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylic acid, is recited in the specification at column 19, lines 41-43 and lines 60-62.

The genus of compounds having diuretic activity is recited in the specification at column 10, lines 29-42. The genus of compounds having calcium antagonistic activity is recited in the specification at column 10, lines 43-50.

Claim 5 is dependent upon claim 4 and recites a Markush group of substances known to have diuretic activity. This list is recited in the specification at column 10, lines 29-42.

Claim 6 is dependent upon claim 4 and recites a Markush group of substances known to have calcium antagonistic activity. This list is recited in the specification at column 10, lines 43-50.

Claim 7 is a method of use claim which is directed to a method for the treatment of angiotensin II mediated diseases in a mammal in need thereof which comprises administering an effective amount at least one of (+)-1-(cyclohexyloxycarbonyloxy)ethyl 2-ethoxy-1-[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylate, 2-ethoxy-1-[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylic acid, or 2-ethoxy-1-[[2'-(2,5-dihydro-5-oxo-1,2,4-oxadiazol-3-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylic acid, or a pharmaceutically acceptable salt thereof, in combination with a compound having diuretic activity or a compound having calcium antagonistic activity. The species, (+)-1-(cyclohexyloxycarbonyloxy)ethyl 2-ethoxy-1-[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylate, is recited in the specification at column 15, lines 24-26, column 17, lines 40-42 and lines 55-57, column, 19, lines 5-7 and lines 21-23, column 20, lines 54-57, column 21, lines 5-8 and lines 59-62 and column 22, lines 16-19.

The species, 2-ethoxy-1-[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylic acid, is recited in the specification at column 16, lines 57-58, column 17, lines 5-7, as the disodium salt at column 18, lines 6-8, column, 19, lines 60-62, column 20, lines 18-20 and lines 35-37 and column 21, lines 25-27 and lines 40-42.

The species, 2-ethoxy-1-[[2'-(2,5-dihydro-5-oxo-1,2,4-oxadiazol-3-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylic acid, is recited in the specification at column 19, lines 41-43 and lines 60-62.

The genus of compounds having diuretic activity is recited in the specification at column 10, lines 29-42. The genus of compounds having calcium antagonistic activity is recited in the specification at column 10, lines 43-50.

Claim 8 is dependent upon claim 7 and recites specific angiotensin II mediated diseases. The angiotensin II mediated disease are recited in the specification at column 10, lines 51-61.

Claim 9 is dependent upon claim 7 and recites a Markush group of substances known to have diuretic activity. This list is recited in the specification at column 10, lines 29-42.

Claim 10 is dependent upon claim 7 and recites a Markush group of substances known to have calcium antagonistic activity. This list is recited in the specification at column 10, lines 43-50.

Therefore, Petitioner submits that the newly added claims 4-10 provide a subgenus relative to the originally issued claims. In view of these new claims, Petitioner believes that this reissue application provides claims directed to a subgenus of the originally filed claims which correct the failure to claim the subgeneric invention invented by Yoshiyuki Inada and Keiji Kubo. All errors which are being corrected in the present reissue application up to the time of filing of this declaration arose without any deceptive intent on Petitioner's part.

7. By this reissue declaration, we desire to seek broadened claims, and, this application for reissue of the original Letters Patent addresses the aforementioned errors in claiming less than we were entitled to claim by including new claims 4-10.

8. We believe that all the errors recited above and being presented for correction in this reissue application arose without any deceptive intention on our part.

The undersigned hereby declares further that all statements made herein of his or her own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

February 13, 2004
Date

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